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Title: Individualizing Pharmacotherapy: A novel optimization strategy to increase smoking cessation in the African American community

Date: 2/3/2022

RESEARCH CONSENT FORM

Individualizing Pharmacotherapy: A novel optimization strategy to increase smoking cessation in the African American community

Sponsor: The University of Kansas Medical Center

Investigator: Nikki Nollen, PhD
University of Kansas Medical Center
913-588-3784

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called "informed consent."
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

This research study will be performed by the University of Kansas Medical Center (KUMC) and based at Swope Health Central, 3801 Blue Parkway in Missouri, or KUMC Clinical Research Unit in Fairway, KS with Dr. Nikki Nollen as the researcher. Participants will have preference of what site they want to use. About 392 people will be enrolled in the study.

Why am I being asked to take part in this study?
You are being asked to take part in this study because you are an African American (AA) smoker who is interested in quitting.

Why is this study being done?
Smoking is the leading cause of disease and death in the United States. African Americans have higher rates of tobacco-related disease than the general population. African Americans smoke fewer cigarettes per day than Whites but have a harder time quitting. We do not know why African Americans have a harder time quitting than Whites. By doing this study, we will examine whether or not changing treatment medications based on an individual's response will help more smokers

quit smoking. We also hope to identify factors that make quitting smoking harder for some African Americans and easier for others. Findings from this study could help researchers figure out ways to improve treatment and make quitting easier for African American smokers.

What is being tested in this study?
You are being invited to participate in a research study to compare how well optimized treatments (OPT) versus usual care (UC) treatments work for smoking cessation. Optimized treatments use available smoking cessation medications but switch between them if one medication is not working for you. Usual care treatments provide the same smoking cessation medication for the entire treatment period. This study is testing whether or not changing treatment medications for those who are not responding to their current plan improves short and long-term quitting.

How long will I be in the study?
Your participation in this study is expected to last about 24 weeks. After initial screening (week 0) you will have 18 weeks of treatment (week 1-18), and a follow-up visit 6 weeks after your last treatment (week 24). You will be asked to visit the clinic 6 times over the course of the study and complete 3 sessions over the phone.

What will I be asked to do?
If you decide to join the study, you will be asked to read and sign this consent form before any study procedures take place.

The study will be divided into 3 phases:

Screening/Enrollment phase: In this phase eligible participants will be asked to complete procedures and answer survey items.

Treatment phase: In this phase you will attend smoking cessation counseling sessions with 4 sessions at the clinic and 3 over the phone. You will also receive your study medication, answer survey items and complete study procedures.

End study follow-up: Six weeks after your last counseling session and dose of medication you will be asked to come to the clinic for tests and respond to survey items during this phase.

You will be randomized (like flipping a coin) to one of 2 groups:

- **Group 1**: This group will receive the nicotine patch and may receive varenicline, also known as Chantix, and Wellbutrin, also known as Zyban depending on response to the medication. Medication will last for 18 weeks.
- **Group 2**: This group will receive the nicotine patch for 18 weeks.

Both groups will receive high intensity smoking cessation counseling.

Below you will find a schedule of events listing all procedures that will occur at each study visit.

Schedule of Events	Week 0	Week 1*	Week 2	Week 3*	Week 6	Week 7*	Week 12	Week 18	Week 24
Eligibility Screening	X								
Informed Consent	X								
Pregnancy Test	x								
Height/Weight	X								
Counseling Sessions	X	X	X	X	X	X	X		
Surveys	X	X	X	X	X	X	X	X	
Receipt of study medication	X		X		X		X		
Return unused study medication			X		X		X	X	
Carbon Monoxide Test	X		X		X				
Saliva Sample	X								
Urine Sample	X						X	X	X
Approximate length of study visit	2 hrs	20 mins	1 hr	20 mins	1 hr	20 mins	1 hr	45 mins	30 mins

Visits marked with an asterisk * will be conducted over the phone. All other visits will be conducted in clinic.

The following is a description of each test and procedure listed above:

Pregnancy test

If you are a woman able to have children, you will be asked to take a pregnancy test. You cannot participate in this study if you are pregnant.

Counseling Visits

You will participate in 15-30-minute counseling sessions to help you quit smoking. Counseling will be completed in person at weeks 0, 2, 6, 12 and by telephone at weeks 1, 3, 7. Counseling will be delivered by our experienced staff who are certified tobacco treatment specialists and have extensive experience treating African American smokers within clinical trials.

Your counseling sessions will be audio recorded. The reason for audio recording sessions is for clinical purposes only. Specifically, to ensure that you are receiving the highest quality of care and that counseling fits your unique needs. No data will be drawn from the digital recordings. The digital files will be identified by a number, not your name, and will be stored on a secure server. No one other than the study team will have access to the recordings. Your audio recording may be kept for 15 years. After that, it will be destroyed.

Surveys
You will be asked questions about yourself, for example, your age, education level, and employment status, your tobacco use history, how smoking and/or quitting makes you feel, and your experience with the quit smoking medications. There is a risk of feeling uncomfortable while answering some of the questions in the surveys. If you feel uncomfortable at any time you may skip a question or stop participating all together.

Medication Dispensing
At week 0 all participants will receive a 2-week supply of the nicotine patch. At weeks 2, 6 and 12 participants assigned to Group 2 will receive another supply of the nicotine patch. Participants that are randomized to Group 1 will be assessed at weeks 2 and 6 and if are not responding to their current medication, as determined by study protocol, will be switched first to varenicline and then to bupropion and the nicotine patch, if applicable. Participants are asked to return unused medication. Those who do not attend medication dispensing visits may be mailed enough of their *current* medication to get them to the next dispensing time point. Instructions on medication use will be provided at each medication dispensing visit.

Carbon Monoxide Test
Exhaled air carbon monoxide (CO) is an immediate, non-invasive method of confirming smoking status. At screening, week 2 and week 6, participants will breathe into a carbon monoxide machine for the purpose of determining smoking level.

Urine and Saliva Samples
Study staff will collect about 1 ounce of urine at weeks 0, 12, 18 and 24. At week 0, a saliva sample will also be collected. Both the urine and saliva samples will be used to test for nicotine and other chemicals found in cigarettes. Additionally, the saliva sample will be used for genetic testing. Your entire genetic makeup will not be determined from this testing. The cells in your body contain deoxyribonucleic acid, or DNA for short. DNA is passed down from your parents. It carries the genes that determine how you look and how your body works. Differences in genes may help explain why a particular drug is effective and safe in some people, but not in others. Differences in genes also may explain why some people get certain diseases, but others do not. Your DNA will only be used for research to understand how your body breaks down nicotine and chemicals from cigarettes and the quit smoking medications.

Melanin Reading
The melanin level in your skin will be measured. Melanin is a pigment that is found in your skin, hair, and eyes. This will be done using a reflectometer which is a device that shines a low intensity light on 3 different measurement sites on the skin.

Text Messages: You can choose to sign up for emails or text messages about this study. The messages will remind you about your study appointments and give you other information that might be helpful during the study. You will pay your standard texting rate. This message service is optional. If you decide to receive messages when the study starts, you can still change your mind later.

What are the possible risks or discomforts?

The study drugs may cause side effects or other problems. You should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.

The common side effects listed below are those occurring in ≥ 5% of patients.

Nicotine Patch:

- Sweating
- Redness or swelling at the patch site
- Irritability
- Problems sleeping or vivid dreams
- Headache
- Dizziness
- Nausea or vomiting
- Abnormal heartbeat or rhythm
- Diarrhea
- Nervousness or restlessness
- Difficulty breathing
- Tiredness

Zyban and Chantix Risks:

- Nausea
- Sleep problems (trouble sleeping or vivid, unusual or strange dreams)
- Headache
- Constipation
- Gas
- Dry mouth
- Dizziness
- Disturbance in attention
- Fatigue
- Skin changes (dry skin or acne

Rarely (less than 1%), patients who take Zyban or Chantix experience

- Gum disease (gingivitis)
- Restless leg syndrome, where you may feel throbbing, pulling, or creeping in the legs and the uncontrollable need to move your legs.
- Ringing in the ears (tinnitus).

Rare but serious side effects occur in ≤ 5% of patients taking Zyban or Chantix and include:

- **Changes in mood:** Some patients feel moody, angry, or have thoughts of hurting themselves or someone else while taking or after stopping the Zyban or Chantix. If you notice these changes stop taking the medication and call your doctor and your counselor right away. Some people with a history of depression or other mental health problems may notice these symptoms may worsen while taking Zyban or Chantix. Feeling moody, angry, and irritable are also symptoms of nicotine withdrawal that people notice when they cut back on cigarettes or stop smoking completely.
- **Seizures:** There have been reports of seizures/convulsions in patients treated with varenicline or Zyban. In most cases, the seizure started within the first month of therapy. If you experience a seizure while on the medication, stop taking the medication and contact your doctor and your counselor right away.
- **Heart or blood vessel problems:** If you have heart disease, taking Chantix or Zyban may increase your chance of certain heart-related events including a change from the normal heartbeat, heart attack, or heart failure. Contact your doctor and your

counselor right away if you experience new or worsening signs of heart disease. New or worsening signs might include trouble breathing, chest pain, or pain in legs when walking.

- **Injury:** There have been reports of car accidents, near-miss accidents in traffic, or other accidental injuries in patients taking Zyban or Chantix. In some cases, the patients reported feeling tired, dizzy, loss of alertness or difficulty concentrating while driving. Do not drive until you know how the medication may affect you.

Allergic Reaction Risks

Some people can have serious skin reactions while taking nicotine gum, nicotine patch, Chantix or Zyban. Symptoms of an allergic reaction are:

- rash
- difficulty breathing
- wheezing when you breathe
- sudden drop in blood pressure (you may feel dizzy or faint)
- swelling around the mouth, throat or eyes
- fast pulse and/or chest tightness/pain
- sweating

If you experience any of these rare but serious symptoms or have a rash with peeling skin or blisters in your mouth, stop taking the study medication and get medical attention right away. If you feel you need immediate medical assistance you should call 911 and you should tell the ER doctor that you are a participant in a research study. Please also contact the study team if you have any of these or any other side effects during the study.

Pregnancy Risks

The drugs used in this study might hurt an unborn child or a child who is breast-feeding. You cannot be in this study if you are pregnant or nursing a baby. You cannot be in this study if you are trying to get pregnant. You will have a pregnancy test before the study starts. You must use birth control during the study. The approved methods of birth control are:

- abstinence
- the consistent use of an approved oral contraceptive (birth control pill or “the pill”)
- an intrauterine device (IUD)
- hormonal implants
- contraceptive injection
- double barrier method (diaphragm with spermicidal gel or condom with contraceptive foam)

There may be pregnancy risks that are not known yet. For this reason, you must tell the researcher right away if you get pregnant during the study. There are no identified reproductive risks related to a male’s use of nicotine patch, bupropion or varenicline.

Are there benefits to being in this study?

You may or may not benefit from this study. Researchers hope that the information from this research study may be useful in the treatment of other patients who smoke.

Will it cost anything to be in the study?

The study will pay for all study-related medical services provided during this study. These services include the study drug, study visits, and study-related procedures such as the urine, saliva, and carbon monoxide tests and counseling sessions as listed in this consent form.

If you are assigned to receive the drug Chantix, it is being provided for the study by Pfizer at no cost to you.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Your insurance may not cover some or all of the standard care services if you are part of a research study. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require Pre-Certification from your insurance company, and representatives of the clinic or hospital will be helping you with that process. Pre-Certification is not a guarantee of payment.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If your insurance denies coverage and you do not qualify for the financial assistance, you will be charged for all bills that are not the responsibility of the study. The study staff will be able to provide more information to you.

Will I get paid to participate in the study?

You will receive payment for participation in this study as outlined in the table below. You will receive a total of $290.00 if you complete the entire study. If your participation in this study ends early, you will be paid only for the visits you have completed. You may also receive $20 for each referral who is eligible and enrolls in this study. You may complete up to 3 different referrals for an additional total of $60.

Week 0	Week 1	Week 2	Week 3	Week 6	Week 7	Week 12	Week 18	Week 24
$30.00	$10.00	$30.00	$10.00	$30.00	$10.00	$30.00	$20.00	$40.00
		$20.00*		$20.00*		$20.00*	$20.00*	

*If you return your unused medication at Weeks 2, 6, 12, and 18 you will receive an additional $20.00 per visit.

You will be given a ClinCard, which works like a debit card. After a study visit or referral enrolls in this study, payment will be added onto your card by computer. The money will be available within 1-2 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

Will the researchers get paid for doing the study?
The research team and the institution (KUMC Research Institute, Inc.) are not being paid to conduct this study.

What happens if I get hurt or sick during the study?
If you have a serious side effect or other problem during this study, you should immediately contact Dr. Nollen at 913-588-3784 or 816-550-5895 or Dr. Allen Greiner at 913-515-4054. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow payment to persons who are injured in research at KUMC.

Do I have to be in the study?
Being in research is voluntary. You can choose whether or not to participate. Even if you decide not to join the study, you can still come to KUMC for services and treatment.

What other choices do I have?
You can choose not to be in the study. Instead of being in this study, you can receive treatment that is already available. Other available treatments include: quitting cold turkey, using other smoking cessation programs, purchasing nicotine gum or patches from the pharmacy, and obtaining a prescription for nicotine inhaler, nasal spray, lozenge, Zyban or Chantix from your doctor. You can have access to smoking cessation medications even if you are not in this study.

How will my privacy be protected?
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. Your medical records at KUMC may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KUMC by Dr. Nollen, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Nollen and the research team permission to share information about you with persons or groups outside KUMC. Your information may be shared with the monitoring company that inspects study data, Bioanalytical Laboratory at the Fairway Clinical Research Center, the laboratory that processes study lab samples, the University of California at San Francisco, the University of Toronto, Jasjit Ahluwalia, MD, MPH, MS, other business partners of the sponsor who help with the study, the U.S. Food and Drug Administration (FDA), and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may

make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use. If your study data is sent outside the U.S., HIPAA privacy protections may not apply; however, the sponsor is still required to keep your data confidential.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Finally, it is important to recognize the limitations of confidentiality. The investigator has a responsibility to report to the proper authorities to prevent serious harm to you or others and instances of abuse to children, elders, or the disabled.

Can I stop being in the study?

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Nollen. The mailing address is Dr. Nikki Nollen, University of Kansas Medical Center, 3901 Rainbow Boulevard, Mail Stop 1008, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of study medication. They are permitted to use and share information that was gathered before they received your cancellation.

Could my participation be stopped early?

This study might be stopped, without your consent, by the investigator or by the FDA. Your participation also might be stopped by the investigator if it is in your best interest or if you do not follow the study requirements.

The investigator, nor the University of Kansas Medical Center will be obligated to provide you with any study medication or treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

Who can I talk to about the study?

Before you sign this form, Dr. Nollen or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT

Dr. Nollen or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

I want to receive visit reminders by (check one):

❑ Email _____ (your email)
❑ Text message _____ (your cell phone number)
❑ Not at all

_____ _____
(Date / Time) (Printed Name of Participant)

_____
(Signature of Participant)

PERMISSION TO BE CONTACTED ABOUT FUTURE STUDIES
I give permission to be contacted about future studies that might require more information:

	YES	NO
About smoking	☐	☐
About any other health related issues	☐	☐

_____ _____
(Date / Time) (Signature of Participant)